

RESPONSE

Currently, claims 15-16 and 18-24 are pending in the present application. The basis of rejection of claims 22 and 23 under 35 U.S.C. § 112, second paragraph, is traversed by the clarifying amendments entered here.

The Examiner has, for the first time with respect to these pending claims, raised the question of enablement in the content of whether or not the presently claimed invention could be practiced without “undue experimentation.” The Examiner has properly noted the factors which have been applied by courts under the In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) precedent. However, the application of the factors does not support the existing rejection. Turning to the specific language of the claim, undue experimentation is not required for any of the recited method steps because the measurements of metabolites are well known in the art and performed routinely in hospitals and laboratories all over the world without substantial expertise or exotic instrumentation. In this particular case, the claims require use of a GC/MS device and such a device readily produces any of the metabolite measurements, a control profile, and readily allows analyte measurements to be compared with a control profile.

The question of whether the method can be practiced does not depend on analyzing any particular metabolite with a mathematical formula that is predetermined for any particular metabolite. In contrast, the claimed invention is expressly recited to involve comparison of a sample with a control profile. Therefore, by definition, the comparison that must be made is a multiplex analysis and examines a plurality of variations in the metabolite profile.

The Examiner appears only to express doubt with regard to the final method step in the sense that the Examiner does not appear to believe that the differences that are revealed by the measurements provided by the claimed method are adequate for the clinician to identify the presence of Down Syndrome in a fetus by performing the appropriate comparison. However, this is not a suitable ground for rejection under 35 U.S.C. § 112, ¶ 1 because any doubt as to whether or not the invention functions as the application claims does not equate to whether one of ordinary skill in the art could actually perform the method as claimed without undue experimentation.

In essence, the Examiner is not questioning whether or not excess experimentation is required, the Examiner is disputing whether or not the method recited actually enables the clinician to successfully accomplish the goal of the method as claimed. The claim recites precisely the method of analysis for the particular metabolites at issue and recites precisely how the analysis must be performed, i.e., between a control profile and a sample obtained from amniotic fluid. The claim also specifies exactly how the presence of Down Syndrome is identified through the identification of a “plurality of abnormal quantities of metabolites.” The fact that the comparison requires a multi-factor analysis cannot necessarily require undue experimentation under § 112.

The question is whether or not the skilled clinician, such as a physician who analyzes clinical conditions based on biochemical testing, could identify the presence of a disease condition based on a number of individual measurements of underlying biochemical mechanisms. On this particular point, no experimentation is required, rather the skilled judgment of one of ordinary skill in the art as described in the specification. If necessary, Applicant is ready and willing to establish through declaration or other evidence that the claimed method can

be readily practice by one of ordinary skill in the art. The Federal Circuit has also noted that a considerable amount of experimentation is permissible when it is routine or provided by reasonable guidance in the application. PPG Industries v. Guardian Industry Corporation, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

Each of the grounds of rejection in the Office Action are overcome by the foregoing amendments.

### CONCLUSION

By entry of this Amendment, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Additionally, the Examiner is invited to telephone the undersigned representative if the Examiner believes that a telephonic interview would advance this case to allowance.

The Commissioner is authorized to charge a three-month extension fee of \$510.00 to Orrick Herrington & Sutcliffe's Deposit Account No. 150665 and any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. 150665.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

By: 

Kurt T. Mulville, Reg. No. 37,194

Dated: March 30, 2006

4 Park Plaza, Suite 1600  
Irvine, CA 92614  
949/567-6700 X 7740 Telephone  
949/567-6710 Facsimile